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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,421	12/08/2003	Henry Nita	PAT-1540	2510
7590		11/14/2005	EXAMINER	
Raymond Sun		VRETTAKOS, PETER J		
12420 Woodhall Way		ART UNIT		
Tustin, CA 92782		PAPER NUMBER		
		3739		
DATE MAILED: 11/14/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

TLC

Office Action Summary	Application No. 10/730,421	Applicant(s) NITA ET AL.	
	Examiner Peter J. Vrettakos	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12-8-03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12-8-03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9,12,14-18 and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kesten et al. (6,251,104).

Independent claims 1, 17

Kesten discloses a therapeutic system (figure 1), comprising;

a guide catheter (13) having a lumen;
a sheath (14) having an elongate body that has a lumen and a distal end, the sheath extending through (figure 1) the lumen of the guide catheter (13); and
a catheter (16) extending through the lumen of the sheath.

Kesten discloses a method of placing the distal end of a catheter at a desired location inside a vessel, comprising:

providing a sheath (14) having an elongate body (26) that has a lumen and an angled (figures 1, 4), distal end (25);
extending a catheter (16) through the lumen of the sheath; and
extending the sheath (14) through the lumen of a guide catheter (13). This is depicted in figure 1 and described in col. 4:8-43; col. 6:1-8.

Dependent claims (below numbers correspond to claims)

2. The system of claim 1, wherein the sheath (14) further includes a proximal end, and a valved fitting (33; figure 4; col. 8:45-50) provided at the proximal end of the sheath.
3. The system of claim 1, wherein the elongate body comprises a main shaft member (26) and a distal shaft member (25), with the lumen of the sheath (14) extending through the main shaft member and a distal shaft member.
4. The system of claim 3, wherein the main shaft (26 part of 14) member is formed of an outer polymeric material (32) having a reinforcing layer (28, 31) embedded therein.
5. The system of claim 4, wherein the reinforcing layer (28, 31) is made of stainless steel (31, col. 8:21-31).
6. The system of claim 4, wherein the reinforcing layer (28, 31) is made of a superelastic alloy (col. 4:61-62).
7. The system of claim 4, wherein the reinforcing layer (28, 31) is a braid (braided or wound, col. 8:40-41).

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8. The system of claim 4, wherein the reinforcing layer (28, 31) is a coil (braided or wound (coil), col. 8:40-41).

9. The system of claim 3, wherein the lumen of the sheath (14) has an inner wall, with a lubricious polymeric material (30) provided on the inner wall of the lumen of the sheath.

12. The system of claim 3, wherein the hardness of the material at the distal shaft (25) member is equal to the hardness of the material at the main shaft member (26). This is strongly inferred in by the uniformity of elements 26 and element 25 depicted in figure 4.

14. The system of claim 1, wherein the catheter is an ultrasound catheter (see patented claim 49 and col. 3:64 through col. 4:4).

15. The system of claim 1, wherein the catheter (16) has a proximal end, the system further including a transducer housing (inherent to the ultrasound disclosure in col. 4:4) coupled to the proximal end of the catheter (16).

16. The system of claim 1, wherein the distal end of the elongate body is angled by an angle of between 10 degrees and 90 degrees (see figure 4; col. 3:35-37).

18. The method of claim 17, further including: advancing the sheath (14) independently beyond the distal end of the catheter (16). This step is anticipated in the patented

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disclosure regarding advancing elements 13 and 14 prior to insertion of catheter 16 (col. 4:37-42). Also, see col. 9:39-44.

20. The method of claim 17, further including: torquing (see rotational language in col. 4:37-43) the sheath to redirect the angled distal end of the sheath.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 13 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kesten.

13. The system of claim 1, wherein the elongate body (14/26; figure 2) has an *outer* surface that is coated with a lubricious coating. This is reversed in the patent. Lubricious coatings 27 and 30 both lie in *inner* surfaces of elements 14 and 13. According to MPEP 2144.04 VI. A, which is presented below, the reversal is obvious. Note also that the reversal here yields the same ends/result, to lubricate/facilitate movement of the two parts.

19. The method of claim 17, further including: retracting the sheath (14) proximal from the distal end of the catheter (16). The same reversal rationale applies here. The

patent discloses advancing and retracting the catheter relative to the sheath. *In re Gazda* indicates these differences between the patent and the Applicant's claims as obvious.

VI. REVERSAL, DUPLICATION, OR REAR-RANGEMENT OF PARTS

A. Reversal of Parts

In re Gazda, 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious expedient.).

2. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kesten in view of Berg et al. (5,680,873).

Kesten is silent regarding a lack of reinforcements in the polymeric material.

Berg discloses an analogous device that propounds the advantages (col. 5:9-14) of reinforcement free polymeric material in the context of the patented device such as cost.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Kesten in view of Berg by leaving out reinforcing material. The motivation would be to keep costs of manufacturing down (Berg col. 5:9-14).

3. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kesten in view of Moorman et al. (6,652,520).

Kesten is silent regarding the outer diameter of the distal shaft member (25) being smaller than the outer diameter of the main shaft member (24).

Moorman discloses in an analogous system and sheath (figure 1e) with the outer diameter of the distal shaft member (14) being smaller than the outer diameter of the main shaft member (13) to improve the rigidity of the main/proximal shaft member (see Moorman col. 8:52-54).

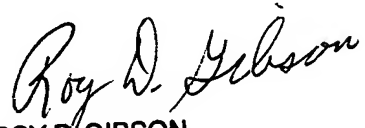
Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Kesten in view of Moorman by designing a sheath with an outer diameter of the distal shaft member of a sheath being smaller than the outer diameter of the main shaft member. The motivation would be improve the rigidity of the proximal portion as posited in Moorman col. 8:52-54.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
November 8, 2005



ROY D. GIBSON
PRIMARY EXAMINER